## HOUSE BILL 2501 By Shepard

AN ACT to amend Tennessee Code Annotated, Title 53, Chapter 10, Part 1, relative to the distribution of certain legend drugs.

## BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 53, Chapter 10, Part 1, is amended by adding the following as a new section:

§ 53-10-110.

- (a) The provisions of this part shall not apply to a person, firm, or corporation who distributes, donates, or otherwise gives away a legend drug that is out of date or beyond its expiration date if:
  - (1) Such drug is distributed, donated or given to an organization that is exempt from federal income taxation under § 501(a) of the Internal Revenue Code as an organization described in § 501(c)(3) of the Internal Revenue Code;
  - (2) The primary purpose of such nonprofit organization is to collect legend drugs donated by another person, firm, or corporation and distribute such drugs to persons who earn less than two hundred percent (200%) of the federal poverty level and who have a medical need for such drugs;
  - (3) The drugs are only distributed by a licensed pharmacist or pharmacy:

- (4) The nonprofit organization does not accept or distribute any drug that is classified and scheduled as a controlled substance pursuant to title 39, chapter 17, part 4;
- (5) Any legend drug so distributed, donated or given to such a nonprofit organization is in solid form and is within one (1) year of the expiration date stated on the drug or its packaging; and
- (6) The drug is unopened, in its original packaging and has not been obviously tampered with, adulterated or damaged.
- (b) Before any legend drug is distributed to a person pursuant to this section, the nonprofit organization shall require the person to read and sign an informed consent.
- (c) The good-faith donor of any legend drug meeting the requirements of subsection (a), to a nonprofit organization of the type specified in subsection (a) for free distribution, shall not be subject to license revocation or suspension or criminal prosecution for a violation of this part, or civil damages arising from the condition of the drug, unless an injury is caused by the gross negligence, recklessness, or intentional conduct of the donor.
- (d) A nonprofit organization specified in subsection (a) which in good faith receives expired legend drugs pursuant to this section, and distributes such drugs free of charge to persons unable to afford them, shall not be subject to criminal prosecution for a violation of this part or civil damages resulting from the condition of the drugs unless an injury results from the gross negligence, recklessness, or intentional conduct of the organization.

SECTION 2. This act shall take effect July 1, 2006, the public welfare requiring it.

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